MAY 1 5 2001

510(k) Summary

This summary statement complies with 21 CFR, section 807.92 as amended March 14, 1995.

Submitter's Name and Address

Aloka Co., Ltd.
10 Fairfield Boulevard
Wallingford, CT 06492

Contact's Name, Title, Address and Telephone Number

Aloka
Kelvin Burroughs
Regulatory Affairs/Quality Assurance Coordinator
10 Fairfield Blvd.
Wallingford, CT 06492
(203) 269-5088

Olympus
Laura Storms-Tyler
Regulatory Affairs, Director
Two Corporate Center Drive
Melville, NY 11747
(631) 844-5688

Device Proprietary Name

Olympus GF-UC140P-AL5 Ultrasonic Endoscope with Aloka SSD-5500 Ultrasound System

Device Common Name

Ultrasound Gastroscope

Classification

The charts below list the Regulatory Class and Device Codes.

Subject	Description
Regulatory Class	Class II
Review Category	Tier II

Code	Description	Regulation
90 ITX	Transducer, Ultrasonic, Diagnostic	892.1570
90 IYN	Ultrasonic, Pulsed Doppler Imaging System	892.1550

Continued on next page

510(k) Summary, Continued

Identification of predicate devices	The GF-UC140P-AL5 is substantially equivalent to the GF-UM30P and the GF-UM130. The two share common indications and some features. The GF-UM30P was cleared in K963023 and the GF-UM130 was cleared in K971660.
Device Description	In examining the GI tract, endoscopic ultrasound may be indicated. The conventional type ultrasound Endoscope does not provide the capability for ultrasonic guidance of endoscopic accessories (i.e. biopsy forceps, aspiration biopsy needles, etc.) The mechanically radially scanning GF-UC140P-AL5 ultrasound endoscope provides this capability since the direction of the sonographic scan coincides with the geometric plane in which the accessory enters.
Probes	The Olympus GF type UC140P-AL5.
Intended Use	The Olympus GF-UC140P-AL5 Ultrasonic Endoscope is intended for use with the Aloka Ultrasound System SSD-5500, EVIS Video System, Light source, documentation equipment, video monitor accessories, (such as aspiration biopsy needles) and electrosurgical unit (except Endoscopic Ultrasound (EUS) guided electrosurgery). This instrument is designed for endoscopic real-time ultrasound imaging, for performing endoscopic ultrasound (EUS) guided needle aspiration (FNA) and for endoscopic surgery within the upper digestive tract.
Safety Considerations	There are no 514-performance standards for diagnostic ultrasound equipment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2001

Olympus Optical Co. Ltd.
% Mr. Donald James Sherratt
Intertek Testing Services NA Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K011314
Trade Name: Olympus GF UC140P-AL5 Ultrasonic Endoscope with the Aloka SSD-5500 Ultrasound System
Regulatory Class: II/CFR 21 892.1570
Product Code: 90 ITX
Regulatory Class: II/CFR 21 892.1550
Product Code: 90 IYN
Dated: March 2, 2001
Received: April 30, 2001

Dear Mr. Sherratt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Aloka SSD-5500 Ultrasound System, as described in your premarket notification:

Transducer Model Number
Olympus GF Type UC140P-AL5

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for

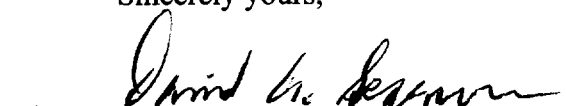
Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,



for Nancy C. Broughton
Director, Reproductive, Abdominal
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

System/Transducer	System
Model	Aloka SSD-5500
510(k) Number	K011314

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P		See Below	
Abdominal		P	P	P		P	P		See Below	
Intraoperative (specify)		P	P	P		P	P		See Below	
Intraoperative Neurological		P	P	P		P	P		See Below	
Pediatric		P	P	P		P	P		See Below	
Small Organ (specify)		P	P	P		P	P		See Below	
Neonatal Cephalic		P	P	P		P	P		See Below	
Adult Cephalic		P	P	P		P	P		See Below	
Cardiac		P	P	P	P	P	P		See Below	
Transesophageal		P	P	P		P	P		See Below	
Transrectal		P	P	P		P	P		See Below	
Transvaginal		P	P	P		P	P		See Below	
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		See Below	
Laparoscopic		P	P	P		P	P		See Below	
Musculo-skeletal Conventional		P	P	P		P	P		See Below	
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E;

Additional Comments: Combined mode operation: B/M, B/PWD, B/Bflow/PWD.
Intraoperative: Gastrointestinal Track and Surrounding Abdominal Organs

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Hoeven

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K011314

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	Olympus GF type UC140P-AL5
510(k) Number	K011314

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		See Below	
Intraoperative (specify)		N	N	N		N	N		See Below	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		N	N	N		N	N		See Below	Non-Cardiac
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E;

Additional Comments: Combined mode operation: B/M, B/PWD, B/Bflow/PWD.
Intraoperative: Gastrointestinal Track and Surrounding Abdominal Organs

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Gregory

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K011314